REMARKS

Reconsideration of the Office Action of August 21, 2009 is respectfully requested. Enclosed is a three month extension of time with requisite fee. Also enclosed is a Supplemental Information Disclosure Statement and requisite fee.

In the present amendment, claim 17 has been amended to convert "the defined size" to "a defined size", with a discussion concerning this change being provided below. Claim 27 has been amended to correct a minor typographical error ("vale" to "valve").

In the Office Action there was indicated that claims 17-21 were considered rejected under 35 USC 112, first paragraph on the basis that the terminology "the defined size" was considered not enabled. There was also raised a 35 USC 112, second paragraph, rejection against these same claims on the basis that the same term was stated in the Office Action to be considered indefinite. Each of these rejections is respectfully traversed. In the first instance, it is submitted that the usage of the terminology was clear in the present application in the sense of what was being referenced, and it was a claim formality issue (which is submitted to more properly be classified as an "objectionable" matter). That is, in the first appearance of the terminology "**the** defined size" there has been presented the phrase "**a** defined size" in place of the "the defined size". Accordingly, any antecedent issue is non-applicable. Also, as an example (that is not intended to be limiting) as to how this terminology is considered to be enabled and understood in the context of the present application, reference is made to the following disclosure appearing on page 3 of the application as one example of the enabling nature of the present application.

> *When an active material is processed to produce small particles, the result is usually particles having a distribution of different sizes, typically a log normal distribution. Thus, whilst particles of different sizes may be present in the material delivered, preferably at least about 25% by mass of the active material is provided in particles small enough to pass the nasal valve, more preferably at least about 35% is in such particles, even more preferably at least about 50% is in such particles, still more preferably at least 75% is in such particles, and even more preferably at least 90% is in*

such particles.

The phrase "defined size" can take on a variety of other meanings within the scope of the present application. For an additional example, also not intended to be limiting, the reference to "defined size" can take on a less than optimum size for one purpose in favor of at least a partial obtainment of a different purpose as illustrated below from the disclosure on page 5 of the present application.

> *In some cases, it is undesirable for particles to reach the lungs and therefore it is preferable that there are very few particles present of a very small size. In such cases, the mean particles size may be higher than the optimum size for turbinate deposition, so as to minimise the presence of very small particles.*

As illustrated from the above few examples (of the potentially many examples of usage of the noted terminology), while "defined size" may be suited for a broad interpretation, such a broad interpretation potential does not constitute indefiniteness and the disclosure is submitted to be sufficiently enabling relative to this terminology. Accordingly, it is respectfully submitted that the objected to terminology is sufficient enabled and clear in the context of the present application. For these reasons withdrawal of each of the 35 USC 112 based rejections is respectfully requested.

With regard to paragraph 3 of the Report, the Examiner rejects claims 1 to 27 and 30 as being rendered obvious based on the combination of Djupesland (US 2004/0112378) and Mishelevich (US 5,363,842). For the reasons set out below it is respectfully submitted that this asserted combination fails to present a prima facie case of obviousness.

In the Office Action there is indicated that Djupesland discloses in paragraphs 211, 210 and 204, a nasal dispenser which uses a gas-tight seal to release an aerosol to the nasal turbinate past the nasal valve. There is also indicated that Djupesland is recognized as not disclosing the claim 1 feature of "substantially preventing further gas flow through the nostril for a predetermined time period to allow the particles to settle on the tissue".

In an effort to remedy this deficiency in Djupesland, there is asserted in the Office Action that Mishelevich discloses the noted claim feature, on the basis that the reference discloses that the patient holds his or her breath for ten seconds to allow small particles to settle and that this teaching is combinable with the teaching of Djupesland to render obvious the claimed invention. This assertion is respectfully traversed.

Prior to discussion how Djupesland and Mishelevich fails to present a prima facie case of obviousness, further reference is made to the discussion of operation of Mishelevich appearing in the first paragraph on column 6 of Mishelevich corresponding to that referenced above by the Examiner in the background portion of Mishelevich.

> *The actual time course of each inhalation is compared to the objective target time course, a comparison derived, and a signal given as to success or failure. At the end of inhalation, a timer is started which runs for the period of time during which the patient should hold his or her breath. At the end of ten seconds (or other period as specified), an auditory and/or visual signal is supplied to the patient. The patient can press a button to signal when breath holding actually ended. In an alternate embodiment, the patient* can signal that event by exhaling (at least initially) back into the hand-held device with the time recorded when an increase in air flow above a specified threshold is detected.

While Mishelevich discloses the above described time feature, a review of the Mishelevich reference as a whole reveals that the above statements concerning timing of Mishelevich are relative to an entirely different usage that is submitted not to carry over to the usage featured in the base reference which is utilized with the nasal cavity. That is, it can be seen from lines 4 to 19 and 20 to 29 of column 2 and lines 43 to 58 of column 1 of Mishelevich that the prior art language of Mishelevich relied upon by the Examiner is describing a situation where it is desirable to deposit products in the lower airways, i.e. the lungs. For example, reference is made to the following description in Mishelevich:

> *These problems are especially evident in the case of aerosol*

> *pharmaceuticals delivered by hand-held inhalers. Hand-held metered dose inhalers (MDIs) are a preferred method of treatment for common respiratory ailments, since the delivery of medication directly to its intended site of action in the lungs allows a reduction in dosage by an order of magnitude or greater. However, certain of these compounds, such as anti-inflammatory corticosteroids, may take many weeks of administration before having a significant effect. Moreover, the inhalation and breath-holding maneuver required for successful delivery of aerosol to the lower airways is counterintuitive and poorly understood by most patients. Thus, a patient may be compliant in using the medication when prescribed, but unsuccessful in using it in the correct manner.*

Therefore, it is respectfully submitted that Mishelevich's teaching concerning the timing of holding ones breath in the context of getting medicament to the lower airways of the lungs, would not have been considered to be a teaching that carries over to "substantially preventing further gas flow through the nostril for a predetermined time period to allow the particles to settle on the tissue". In other words, the reference to holding breath in the context of Mishelevich is submitted not be a teaching that one of ordinary skill in the art would have taken as being applicable to the nasal region (e.g., deposits in the intermediate nasal turbinate region which is positioned as to readily create the potential for undesired passage of deposit material past as wall as insufficient passage to that location during the inhalation stage).

Further, in Mishelevich the step of holding one's breath is also combined with inhaling at a slow enough rate to minimize loss of medicine through impaction in the throat and upper airways, for example at an inhalation rate of below one litre per second. This is further indicative of the limited usage teaching of Mishelevich which is only intended to be used for deposition of particles in the lungs, using an oral inhaler not a nasal inhaler. Therefore, it is respectfully submitted that a combination of the two prior art documents does not directly lead to the claim 1 invention.

At paragraph 4 of the Office Action there is indicated that claims 28 and 29 are rejected as being obvious in the light of Djupesland, Mishelevich and Ruskewicz (US 5,971,951). The Office Action further includes an indication that Ruskewicz discloses a microprocessor for aerosol devices that discloses both audible and visual displays and that the audible display activates if the patient has not delivered the full amount of medication (column 36, lines 50 to 52) and a visual display after a predetermined dose has been delivered (column 36, lines 47 to 49). Applicants, note however that the purpose stated in that same paragraph is to count the number of doses administered, to indicate when more doses should be administered, but it does not time the actual administration. The only timing that does go on is to indicate to a patient when to take further doses, which is described at line 30 of column 36. Therefore, it is respectfully submit that, in addition to failing to remedy the above noted deficiency relative to the base references of Djupesland and Mishelevich, Ruskewicz also fails to teach means for indicating when a predetermined time period has lapsed after actuation of the delivery means, so as to allow the particles to settle on tissue.

Also, for similar reasons as to why claim 1 is allowable, it is respectfully submitted that the remaining independent claims 27-29 (as well as their dependents) are in condition for allowance.

Applicants respectfully submit that the application as a whole stands in condition for allowance and confirmation of the same at the Examiner's earliest convenience is earnestly solicited.

Also, if any fees are due in connection with the filing of this Amendment, such as fees under 37 C.F.R. §§ 1.16 or 1.17, please charge the fees to Deposit Account 02-4300; Order No.033335R028.

Respectfully submitted,

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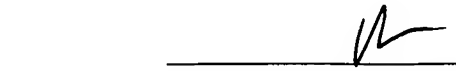

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